

August 24, 2010

Donald Berwick, MD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
Room 314G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1503-P: Proposed Rule for to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2011

Dear Administrator Berwick:

On behalf of the American Society of Nephrology (ASN), a not-for-profit organization of 11,000 physicians and scientists dedicated to helping nephrologists provide the highest quality of patient care possible, thank you for the opportunity to provide comment on the Centers for Medicare and Medicaid Services (CMS) Proposed Rule for Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011.

ASN promotes excellence in the care of patients with kidney disease, fostering innovative research related to renal disease, providing continuing medical education to enhance understanding and treatment of renal disease, and advocating for policy that improves the quality of care delivered to our patients. As such, when considering changes in policy, ASN focuses on the impact of modifications on the quality and availability of patient care.

ASN respects and appreciates CMS' willingness to collaborate with the renal community to address the important issues and challenges facing kidney disease patients and providers in order to offer the highest-quality care. In light of the Society's overall devotion to the patients its members treat, ASN submits the following comments regarding the proposed rule.

CMS should ensure that home dialysis policies remain flexible and appropriate for the unique home dialysis patient population, and that any changes to the existing policy do not create a disincentive to offer home dialysis care. (p. 219)

We appreciate CMS' dedication to promoting appropriate, high-quality care for ESRD patients who dialyze at home using peritoneal dialysis (PD) and hemodialysis (HD). We agree with the Agency that as a general guideline, it is best for home dialysis patients to have monthly face-to-face visits with their nephrologists. Regular, in-person interactions between patients and their nephrologists are an integral part of high-quality care, and we concur that monthly face-to-face encounters are clinically appropriate. However, for certain patients who dialyze at home, a monthly face-to-face visit may not always be necessary or feasible, and linking it to physician reimbursement may impose an undue burden on the patients.

The home dialysis patient population is, as a rule, different from in-center HD population. These individuals typically elect to dialyze at home to maintain independence, and sometimes because they reside at a great distance from a dialysis facility. Importantly, home dialysis patients (and often their families) are highly trained in self-care and many are significantly healthier than in-center patients.

Notwithstanding the relative autonomy of home dialysis patients, nephrologists are often closely involved in the overseeing the care of these patients on an ongoing basis. Most home dialysis programs have a nurse available on-call 24-hours a day, seven days a week. Patients depend on these nurses for troubleshooting – not only for dialysis-related but also non-dialysis related medical problems. The nurses function as a part of health-care team under the leadership of the nephrologist and can call the physician to appropriately respond to the patients' needs. The nature of these ongoing contacts of patients with the nephrologist directly or through the nurse pertain to issues such as management of blood pressure, control of blood sugar for diabetic dialysis patients, management of problems of fluid overload and the consequent need to adjust dialysis prescription, and management of complications of the therapy like peritonitis in peritoneal dialysis patients.

Furthermore, patients regularly obtain blood tests, either at the dialysis unit or at a health-care facility close to where they live. Nephrologists review these laboratory results and make changes in treatment; these changes include adjustment of erythropoietin or vitamin D dose, administration of iron, and adjustment of prescription to achieve target solute clearances. Many of these activities often occur outside the face-to-face visit with a patient. As such, if a nephrologist does not have a face-to-face visit with a home dialysis patient, it does not necessarily mean that his or her physician is not actively monitoring the patient's condition and providing necessary oversight to maintain optimal health. Indeed, there does not seem to be a relationship between the frequency of face-to-face visits and tangible or relevant outcomes in patients with chronic diseases, including end-stage renal disease (*Plantinga et al, J Am Soc Nephrol 2004; 15: 210-4*). Moreover, the increase in patient-physician contact following the implementation of the recent CMS regulations for in-center HD patients did not lead to any improvement in either patient outcomes or health-related quality of life (*Mentari et al, Am J Kidney Dis 2005; 46: 621-5*).

Accordingly, we have several reservations about CMS' proposal to require monthly visits—with no exceptions--and are concerned this may result in unintended consequences on patient care and quality of life.

In addition to the uncertainty about linking physician reimbursement to a face-to-face visit with a home dialysis patient, we are concerned that a mandatory monthly visit may create unnecessary health care costs, and create a financial and social burden for patients. For example, we question whether it would be appropriate to mandate that an experienced home dialysis patient who resides hundreds of miles from the nearest dialysis center, has highly satisfactory lab test values, and remains in consistent communication with his or her nephrologist make a monthly visit to the facility—especially if this would require the patient to take a day off of work, pay for a day of childcare, and cover travel costs. The burden may be particularly onerous during the winter months for patients who live in areas that get frequent or heavy snow-storms.

We also wish to make a special note that pediatric home dialysis patients may experience exceptional circumstances due to the scarcity of pediatric nephrologists and remote geographical locations that would make monthly face-to-face visit requirements more difficult to fulfill. Furthermore, such a requirement may increase absenteeism for school-going children and impact the future productivity and gainful employment of young dialysis patients. There is also a small population of pediatric home dialysis patients who are ventilator-dependent, and for whom travel for an in-person visit may be dangerous.

Moreover, if a patient decides to skip a monthly visit, the nephrologist would not be eligible for reimbursement for that entire month. We believe this would unfairly penalize nephrologists, in particular because this penalty does not take into account the important and extensive remote patient management duties nephrologists conduct throughout the month. For the reasons listed above, we are also concerned that this proposal may present a disincentive to offer home dialysis—a dialysis option which ASN strongly supports offering—to patients.

In summary, face-to-face visits are a vital component of high-quality care for home dialysis patients and, whenever possible and appropriate, should occur monthly. However, we believe that mandated monthly visits do not constitute the most appropriate plan of care for all patients on home dialysis. As such, we request that CMS not to change the current status for reimbursement for home dialysis care. Should the Agency pursue modifications to current policy, we further encourage the Agency to work with the nephrology community to ensure reasonable flexibility and avoid any disincentives to providing home dialysis care.

CMS should finalize its proposal to include the Kidney Disease Education Benefit in the list of telehealth eligible services. (p. 246)

ASN thanks CMS for its proposal to add individual Kidney Disease Education (KDE) services to the list of approved telehealth services for CY 2011 on a category 1 basis, reported by HCPCS code G0420. As expressed in the society's comments regarding the CY2010 Proposed Physician Fee Schedule, we believe educational interventions are an extremely important component of CKD care, as they may help pre-dialysis patients delay the onset of renal replacement therapy, thus preserving their quality of life as well as reducing costs to the Medicare program. Because many ESRD patients reside in rural areas and do not possess readily available access to important services such as KDE, we believe that this new proposal is an important step in ensuring the availability of high-quality kidney care in remote areas. ASN appreciates the Agency's responsiveness to our concerns in this regard.

Having expressed similar support for addition of telehealth services to the list of approved telehealth services, the society is also appreciative of the Agency's proposal to include group KDE services to the list of approved telehealth services for CY 2011 on a category 1 basis, reported by HCPCS code G0421 for group KDE services.

Beyond reiterating our support for these proposed changes, we also encourage the agency to maintain its existing policy regarding the qualified providers for KDE services: "a physician, nurse practitioner, clinical nurse specialist, or physician assistant," or a provider of services located in a rural area (defined as facilities located outside of a metropolitan statistical area (MSA) or defined as rural under section 6 1886(d)(2)(D) of MIPPA). We believe this policy appropriately ensures the quality and content conveyed to patients in educational sessions and is concordant with the intent of MIPPA.

CMS should finalize its proposal to waive the coinsurance/deductible responsibility for the Hepatitis B Vaccine (p. 349)

We appreciate CMS' proposal to waive the coinsurance/deductible responsibility for the Hepatitis B vaccine for patients who are on dialysis or are immunosuppressed for intramuscular use. Removing barriers to preventive care is a vital component of preserving the health of these especially vulnerable patient populations. We concur with CMS that this action is warranted in light of the US Preventive Services Task Force's most recent vaccine recommendations, which a grade of A to the hepatitis B vaccine and its administration, as well as the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices currently recommendation for influenza, pneumococcal, and hepatitis B vaccines.

CMS should finalize its proposal to update the ESRD composite rate with the ESRD market basket increase and apply a positive drug add-on adjustment. However, the Agency should also bear in mind the significant limitations of older drug expenditure data. (p. 440)

CMS proposes to update the basic ESRD case-mix composite payment system for CY 2011 and to continue updating the composite rate through 2013. ASN recognizes that this is necessary to determine the composite rate portion of the blended payment system that will go into effect for facilities that elect to undergo the four-year transition (phase-in) of the new ESRD PPS beginning January 1, 2011. ASN supports the Agency's proposal to increase the ESRD composite rate portion of the blended payment amount by the ESRD market basket, as delineated in the ESRD Final Rule.

However, as the society expressed in its comments regarding the ESRD Proposed Rule, we are concerned that the 2006 - 2009 data used to calculate the drug add-on adjustment to the composite rate may not accurately predict future ESA usage.

Practice patterns have evolved significantly in the past several years, especially in light of randomized controlled trials results (beginning with CHOIR in 2006 and continuing through TREAT in 2009) as well as the Food and Drug Administration (FDA) Risk Evaluation and Mitigation Strategy (REMS) "black box warning" for ESAS, instituted in 2010. Accordingly, the range of hemoglobin targeted has changed over this time period and nephrologists today aim for relatively lower levels. Hence, the rate of increase in ESA use is likely to be lower than what would be predicted based upon the 2006-2009 data. Using data from a period when ESA use has been changing may lead CMS to over-estimate the increase in ESA use. This would, inappropriately, lead to reductions in payment per unit dose. While recognizing the challenges of rapidly obtaining data, it is important to bear in mind the significant limitations of older data. As CMS continues to update the drug add-on during the phase-in period of the new bundled payment system, ASN would be pleased to discuss this issue in greater detail with the Agency.

Despite our reservations about the limitations of the data, overall ASN supports CMS' proposal to increase the drug add-on adjustment. As ASN has previously commented, this proposal reflects Congress' selection of the phrase "annually increase" in the Medicare Modernization Act (MMA). This phrase is clearly intended to prevent negative updates to previous years' rates.

CMS should bear in mind the administrative burdens associated with the PQRI relative to the incentive. (p. 530)

ASN appreciates that CMS has created the opportunity for providers to be rewarded for offering and documenting provision of high-quality care. However, we believe that in order for such a program to be optimally successful, incentives must be commensurate with the burden of documentation. We appreciate that the current levels of PQRI payments are legislatively mandated but we believe it is important to point out that the proposed 1 percent is not highly likely to drive quality. We are also concerned that in future years as the payment incentives continue to decline—and ultimately vanish—the costs of documentation may well outweigh savings derived from providing higher quality care.

Conclusion

On behalf of the ASN, thank you for your willingness to consider our comments for the proposed rule for CY 2011. We believe that our proposed recommendations will prove helpful in formulating policies that continue to promote accessible, high-quality patient care. To discuss ASN's comments, please contact ASN director of Policy and Public Affairs, Paul C. Smedberg, at (202) 416-0640 or at psmedberg@asn-online.org.

Sincerely,



Sharon Anderson, MD, FASN
President, American Society of Nephrology